

MAR 20 2000

K000057

Attachment VII: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER: Radionics Inc,
76 Cambridge Street
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 272-2428

Contact: Kevin J. O'Connell
Senior Regulatory Engineer

PROPRIETARY NAME: Radionics Lumboperitoneal Shunt

COMMON OR USUAL NAME: Lumboperitoneal Shunt

CLASSIFICATION CODE: Shunt, Central Nervous System and Components
21 CFR, Section: 882.5550

PREDICATE DEVICE: PS Medical's Lumboperitoneal Shunt, K831396

DESCRIPTION: The Radionics Lumboperitoneal Shunt consists of barium impregnated silicone tubing with flow holes at the proximal end and slits at the distal end. The slits control the flow of CSF through the shunt and prevent retrograde flow. The shunt is available in a standard design and a T shape design. The overall length of both shunts is 84 cm. Both are provided sterile for single use only.

INTENDED USE: Intended to shunt cerebrospinal fluid (CSF) from the lumbar subarachnoid space to the peritoneum.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 20 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kevin J. O'Connell
Senior Regulatory Engineer
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K000057
Trade Name: Radionics Lumboperitoneal Shunt
Regulatory Class: II
Product Code: JXG
Dated: January 7, 2000
Received: January 10, 2000

Dear Mr. O'Connell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

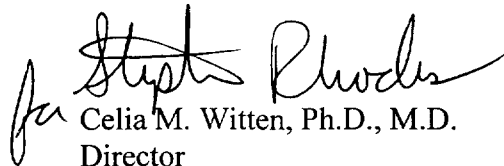
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. Kevin J. O'Connell

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the printed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Page 1 of 1

Device Name: Radionics Lumboperitoneal Shunt

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Steph Plouffe
(Division Sign-Off)
Division of General Restorative Devices K000057
510(k) Number _____

Over-The-Counter Use

(Optional Format 1-2-96)